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RESEARCH REPORT

Federal Policy

on

PCB Contamination

of the

Food Chain

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I. SUMMARY

Polychlorinated biphenyls (PCB's), along with DDT and such heavy metals as mercury, lead and cadmium, are examples of chemicals that are widely dispersed throughout the environment. PCB's and DDT are similar insofar as they are very persistent chemicals that enter the food chain and tend to accumulate in the fatty tissue of marine life, birds and mammals.

Scientific studies indicate the widespread presence of PCB's in many different organisms, including man. Toxicological studies have demonstrated the mortality of marine life with concentrations of PCB's and several other studies have outlined the effects on game birds and domestic birds. However, the effects of PCB on man is largely unknown and federal agencies are only beginning to conduct research in this area.

Research Status

Monsanto is the sole source of PCB's in the U. S. and has conducted most of the research to determine the toxic effects of PCB's on a variety of animals. Monsanto has also been working on the difficult problem of developing analytical methodology for accurate detection and measurement of PCB's. The firm has been willing to share its findings with the federal government, and the Food and Drug Administration has admittedly been awaiting results from Monsanto's research in order to gauge its own research priorities.

On August 5 (this week), FDA scientists are meeting to evaluate their existing research program, which has been minimal, at best, but will undoubtedly be expanded in the near future. Several other federal agencies are conducting research on PCB's. The Department of Agriculture does not have a large research capability in this area, but has been looking at PCB milk contamination and its effects on cows. EPA's contract research

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in this area has been confined mostly to detecting PCB's in human tissues, a program recently expanded. EPA's Office of Pesticides recently acquired a laboratory in Florida which has been working for over a year on the testing for PCB's in marine life. Other laboratories across the nation, operated by the Bureau of Wildlife and Sports Fisheries, have been among the first to detect PCB's in marine life, wild birds and other wildlife, and will continue to test for these compounds regularly. In order to develop a federal policy or program to deal with PCB's and other toxic substances, the Office of Science and Technology, Executive Office of the President, is actively engaged in case work on PCB's to evaluate available information and advise the President. They are evaluating the various research activities on PCB's which are being performed by a variety of federal and private institutions.

Regulation Status

Inputs into the food chain can come from several directions, many of which are unintentional and unknown. Thus, several agencies of the federal government currently exercise some degree of control over PCB contamination of food and the environment.

First and foremost is the control over PCB contamination of red meat and poultry, exercised by the Department of Agriculture, and of milk, animal feeds and all foods as exercised by the Food and Drug Administration (FDA). This regulatory authority has existed for several decades and, in recent years, has served to detect PCB's in poultry, fish, and milk.

Preventing contamination of food stuffs, however, is a much more difficult problem than detecting it in food products and animals. The Office of Pesticides of the Environmental Protection Agency (previously of the Department of Agriculture) has prohibited the use of PCB's in pesticides, thereby preventing their application to agricultural crops.

The separate offices of Air and Water Programs of EPA have not yet exercised regulatory control over air and water emissions of PCB's, though the emission of PCB's during municipal incineration will soon be regulated to some degree by particulate standards. Additional restrictions on air and water emissions will be enacted by EPA in the future, but these regulations deal primarily with intentional or known emissions of PCB's--virtually all of which have been eliminated or have been placed under voluntary control. EPA does not yet have authority to control the disposal of products containing PCB's to prevent runoff into streams and leachate into ground water supplies.

By far the most effective existing control over PCB's remains outside the government at the point of origin. Monsanto, sole U. S. supplier of PCB's, has voluntarily restricted distribution of PCB's to what it defines as "controlled" industrial applications. However, it was a "controlled" application that leaked PCB's in the recent chicken feed incident. This suggests that the monitoring of controlled PCB applications is not completely thorough. Monsanto marketing and monitoring activities will be crucial to the overall PCB control. Therefore, the most important operating controls at this time are Monsanto's voluntary restrictions on distribution and the USDA and FDA ability to keep contaminated meat and food products from the market.

Legislative Status

The Council on Environmental Quality has taken the stand that the current approach to controlling pollutants in the media in which they primarily occur is not satisfactory in regulating widely spread toxic chemicals such as PCB's. As an example, CEQ points out that, even though mercury contamination from industry was controlled using existing water pollution authority, mercury still is being released to waterways from various smaller sources such as school labs and medical labs.

CEQ argues that control of hazardous substances should concentrate on the substance itself rather than on the media in which it is found. Based on the CEQ report on toxic substances, the Administration has introduced a bill (HR 5930, S 1478) that would authorize EPA to restrict or prohibit the use or distribution of chemical substances produced in commercial quantities in order to protect the health or environment. An amendment to the bill has been introduced and Senate Commerce Subcommittee hearings have been held. Senator Muskie has also introduced a bill similar to the Administration bill but no hearings have been held and it is unlikely that they will be held this Congressional session.

It is not likely that the Administration bill will pass either the House or the Senate during this session.

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II. OUTLINE OF THE SCIENTIFIC PROBLEM

I. Introduction

In the last four years there has been an increasing realization that polychlorinated biphenyls (PCB) pose a potential environmental danger. For many years, chemists investigating substances contaminated by DDT did not know the identity of PCB materials and ascribed them to unknown metabolites or breakdown products of insecticides. Since 1966, scientists have become more knowledgeable about the extent of PCB contamination.

II. Properties of PCB's

The properties of PCB's make them potentially significant environmental contaminants. They have high boiling points, excellent thermal stability resistance to both acids and basic hydrolysis, general inertness and resistance to oxidation. In addition to low water solubility, PCB's share with DDT a high solubility in fats and the ability to become absorbed into mud and other suspended particles. Due to their non-biodegradability, PCB's have shown up with increasing concentrations in many species.

III. Entrance Into the Environment

PCB's act like DDT in their passage through the environment, but DDT enters the environment deliberately, primarily as a pesticide, and PCB's enter it principally by accident. Carbonless reproducing paper, plastic film containing PCB's as plasticizers, spent fluorescent light ballasts, coatings and adhesives with PCB's--all may end up at the local incinerator upon disposal. PCB's do not burn readily and are only vaporized. The vapors are carried into the atmosphere where they collect on particulate matter. Air currents in the lower troposphere carry the

particles worldwide to be finally deposited on the ground by rainfall. The global distribution pattern of PCB's and DDT is quite similar to that of radioactive fallout. Runoff of industrial wastes from dumps is another source. A third source is from manufacturing plants making PCB's where effluents may escape through stacks or ventilation systems or pass through waste treatment plants. Erosion of surface coatings and spoilage of heat transfer and dielectric fluids are other major routes into the environment.

IV. Contamination of the Food Chain

PCB's enter the food chain when plants and photoplankton absorb nutrients from the soil or water. Animals eat the plant material and concentrate the PCB in their fat. Carnivores then prey upon these herbivores and on each other and concentrate the PCB even further.

PCB's go from plankton in the sea to small fish, to larger fish, to birds which prey on these fish. In each passage through the food chain the contaminant will become further concentrated with little loss. When man eats the fish or bird, or when domestic animals eat processed fishmeal, the persistent PCB lodges in the body fat along with DDT and other chlorinated pesticides.

PCB's that are absorbed by plants (hay, grain foods) are fed to domestic animals with resulting concentration of the PCB.

Thus PCB's enter the natural and the domestic food chain and eventually may concentrate in man. The spread and concentration of PCB's in man is largely unknown.

V. Toxic Effects in Fish and Birds

A number of scientists have conducted experiments, testing for PCB's in fish and birds. The following cases indicate some of the findings.

1) PCB's at a concentration of 5.0 ppb (parts per billion) caused 72% mortality of pink shrimp in 20 days with an accumulation of 33 ppm PCB. (Duke, T. W., J. I. Lowe, and A. J. Wilson, Jr. 1970 Bulletin Environ. Contam. Toxicol. 5:171-180.)

2) Shrimp exposed to 10 ppb Aroclor 1254 (PCB) for 48 hours, accumulated 1300 ppb PCB, representing a 130 fold concentration. (Reynolds, L. M. 1969 Bull. Environ. Contam. Toxicol. 4:128).

3) Fish-eating birds such as the white-tailed eagle were found to have as much as 14,000 ppm of PCB's. Peregrine falcons from the California coast had as much as 2000 ppm in their fatty tissue. (Riseborough, R. W., et al. 1968. Nature, 220:1098-1102).

4) One ppb of the PCB Aroclor 1254 causes a 20 per cent decrease in oyster shell growth. (Duke, Lowe and Wilson, 1970.)

5) Birds dependent upon fish have suffered widespread mortality and population decline in the north and Baltic seas as well as off the coast of California. (Jensen, S. A. et al. 1969. Nature 224: 247-250.)

6) Aroclor 1242 fed to chicks produced the same characteristic effects as chick edema factor. "Gross pathology included hydropericardium, hydroperitonium, enlarged heart, liver and kidneys, and hemorrhage of internal organs. Microscopically the kidneys showed marked tubular dilation and numerous casts." Apparently chickens and birds are quite sensitive to residues of chlorinated hydrocarbons. (McClune, University of Missouri).

VI. Toxicology of PCB in Man

In man, chlorinated biphenyls act on the skin and have a toxic action on the liver. The liver lesion is an acute yellow atrophy. The higher the chlorine content of the diphenyl compound, the more toxic it is liable to be. Skin lesions, known as chloracne, consist of small pimples and dark pigmentation of exposed areas. Later pustules develop. (Sax, Irwing, "Dangerous Properties of Industrial Materials," Third Ed., Van Nostrand-Reinhold, N. Y., 1968.)

PCB's have been found in human fat and in a series of mother's milk samples along with DDT residues. DDT has been shown to be tumorigenic (i.e. carcinogenic) and because PCB has a similar chemical structure it may be carcinogenic also. (Innes, J. R. M., et al. 1969. J. Nat. Cancer Inst. 42:1101-1114.)

VII. Difficulties in Detecting PCB's

It was in 1966 that PCB's were first identified during DDT testing from wildlife samples. Since then, rudimentary testing and analysis methods for separation and identification have been developed. One of the main difficulties in analysis results because of the similarity between DDT and PCB's. In gas-liquid chromatographic analysis it is difficult to separate PCB's from DDT and other interfering compounds due to overlapping. It takes a specifically trained professional to pick out the correct peaks because one PCB compound may contain 4 to 8 different molecular species and isomers.

FDA is beginning development of analytical methods for PCB. Refined methodology is one to two years away.

VIII. Toxicity Testing by FDA

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FDA has conducted few if any toxicity experiments. Plans have been formulated to work on the teratology (production of physical defects during pregnancy, i.e. thalidomide) carcinogenesis and mutagenesis of PCB's, but this work will not be completed for some time.

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FDA apparently has relied on a Monsanto two year chronic toxicity test to produce reliable information. This test will be completed in another year.

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III. CURRENT FEDERAL ACTIVITY

1. Regulatory System

A. PCB's in Foods: Existing Controls

Once PCB's become a direct contaminant of the food chain by entering fish, meat, poultry, dairy products and related foodstuffs, they come under the regulatory authority for foods shared by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture.

U.S. Department of Agriculture

Control over PCB's in red meat and poultry results from USDA's authority to inspect meat and poultry for wholesomeness both before and at the point of slaughter. As provided by the Federal Meat Inspection Act (21 U.S.C. 601 et seq), and the Poultry Products Inspection Act (21 U.S.C. 451-469), USDA inspectors can label as "inspected and condemned," meat and poultry products which are considered "adulterated" according to the Food, Drug and Cosmetic Act (21 U.S.C. 301-392). According to this Act, a food is adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to health." (Sec. 402 of 21 U.S.C.). Therefore, in the recent episode concerning PCB's in chicken in North Carolina, USDA adopted an FDA guideline (not an off-tolerance level) concerning the acceptable level of PCB's in chickens, namely 5 ppm (parts per million) and condemned chickens which exceeded this level. According to the Poultry Inspection Act, once condemned, such poultry carcasses and poultry products must be destroyed, and none of the products can be introduced into interstate commerce.

Most meat and poultry inspection is a visual operation, but the Field Operations Division of the USDA (Dr. Victor Berry, 388-4260, Deputy Director, Field Operation Division, Consumer and Marketing Service) carries out both continuous, and emergency monitoring of poultry and meat tissue. For several years they have had an ongoing surveillance program to test for chlorinated hydrocarbons in animal tissue. Roughly 3000

meat and 3000 poultry samples are requested for testing each year for chlorinated hydrocarbons. They have been testing specifically for PCB's in red meat and poultry since January, 1971. Selected samples are tested daily from slaughtering plants across the nation. In cases such as the detection of specific contaminants in an area, USDA will carry out more intensive testing procedures to locate the nature and extent of contamination. Thus in the recent episode of PCB's in chickens, more intensive testing was done in a 10-state area to check for contamination. It is not clear if the continuing analysis of chlorinated hydrocarbons distinguishes PCB's from DDT and other organo-chlorine compounds.

As for PCB's in milk, the USDA could exercise some control via the Agricultural Marketing Act of 1946 (7 U. S.C. 1621-1627) authorizing grading, inspection and certification of fluid milk as an agricultural product. However, most milk surveillance occurs on the state and local levels. The federal role has been largely advisory, and has occurred through the FDA.

USDA has recently acquired authority to inspect eggs under the Egg Products Inspection Act (84 Stat. 1620), and a number of USDA and FDA spokesmen have indicated that they will be taking a closer look at egg and egg product contamination. The Act provides inspection of certain egg products by USDA and calls for uniformity of standards for eggs in interstate and foreign commerce. Any egg or egg product can be found adulterated for the same reasons as meat and poultry. The Act passed both houses of Congress in December, 1970.

Food and Drug Administration

FDA control over toxic food contaminants is based on the Food, Drug and Cosmetic Act (21 U.S.C. 301-392) authorizing FDA to prohibit the sale of any adulterated food. FDA can also prohibit the use of certain food additives or can establish tolerance levels for the amount to be used. So far, FDA has published no tolerance level for PCB's as a food additive. Hence, in the recent chicken episode, the contaminated chicken

feed fishmeal was condemned on the basis that it contained an illegal food additive for which no tolerance was allowed. The contaminated poultry remained under USDA authority which adopted the FDA guideline (5 ppm) for determining safe broilers. The guideline is not to be confused with a food tolerance level. It was determined by a special FDA committee of toxicologists and other specialists and was intended for administrative use only, that is, as a means for deciding the fate of contaminated food and not as a public directive to industry concerning an allowable level of additive. FDA set a 5 ppm level on a whole (chicken) tissues basis, and a 5 ppm level for chicken fat. Since the PCB concentration runs much higher in the fatty tissues, the allowable level was more stringent than if merely a whole tissue limit had been set.

According to Richard Ronk, Chief of Guidelines and Compliance Research in the Food Bureau, FDA will be looking at eggs in the Southeast grading area exposed to the contaminated fishmeal during the past weeks. He also offered the judgment that PCB's are not as ubiquitous as one would think, and that their occurrence in foods results largely from accidents.

FDA has 17 district offices in major cities and over 100 resident posts across the nation where local or regional products are tested. Each district makes a judgment as to the commodities to be tested. According to Frank Thompson of the Division of Compliance Programs, the Food Bureau does have a program to cover all pesticides in food, plus a specific program to detect PCB's in the food supply. They also test fluid milk in the various districts for these contaminants, though the state and local authorities have assumed most responsibility here.

The Bureau of Veterinary Medicine of the FDA is in charge of regulating animal feed and was responsible for condemning the fishmeal used as animal feed in the recent episode. Though they are mainly responsible for drugs in animal feed (Sec. 512 of the Food, Drug and Cosmetic Act), they have jurisdiction over sampling and analyzing unsafe

additives in animal feed. According to James O. Gosling, Director of the BVM's Division of Compliance, they were "on top" of the fishmeal issue when it occurred.

Control Options

Inssofar as PCB's in meat, poultry, eggs, and other products under their jurisdiction are concerned, the USDA has sufficient authority to control dispersal of the above contaminated products via interstate commerce. Criticism of USDA involves mostly the issue of how they exercise their existing regulatory authority, not that they are ineffectual due to lack of authority. Similarly, the FDA has broad powers over the introduction into interstate commerce of adulterated foods. One control option FDA has not exercised, relevant to PCB's, is Section 406 of the FIC Act, enabling them to set tolerances for poisonous ingredients in foods which cannot be avoided by good manufacturing practices. This section has never been used, though there was an effort to use it to set a pesticide tolerance level. It is unlikely, however, that any tolerance level could be set for PCB's in foods until their toxic effect on humans is better known.

B. PCB's in Pesticides: Existing Controls

Office of Pesticides - Environmental Protection Agency

In 1970, partly in response to complaints raised by Congressman Ryan (D-N.Y.), the Secretary of Agriculture agreed to ban the use of PCB's in pesticides and to cancel registration for pesticides containing PCB's. However, at the time of this agreement, the use of pesticides had been limited, and Monsanto had already agreed not to market them for these applications. No cancellations were ever issued, since the concerned pesticide (insecticide) manufacturers changed the composition of their end-product voluntarily. (Pesticide control has been transferred from the Department of Agriculture, Pesticide Research Division, to the Office of Pesticides, EPA.)

C. PCB's in Industrial Applications: Existing Controls

Monsanto

In response to discoveries of PCB's in birds, Monsanto Corp., sole U. S. supplier of PCB's (trade-named Aroclor), announced in the summer of 1970 that it would "restrict sales of PCB's only to those applications where their unique fire resistance properties are important and where it is possible to control collection and regeneration or incineration of spent material." They therefore announced the following actions:

- 1) Discontinue sales of PCB's for all general plasticizer applications. - August 30th, 1970.
- 2) Phase out the PCB's as components of industrial and hydraulic fluids where control of spillage and collection of spent material is not possible--the major part of this program will be completed within six months.
- 3) Continue sales of PCB's as dielectric fluids for transformers and capacitors, cooperating with customers collecting spent and arced fluid for regeneration and/or incineration.
- 4) Continue sales of PCB's as fire resistant heat transfer fluids ensuring modification to systems designed to make provisions for collection of spills and leakage. Collect spent fluid for regeneration and/or incineration.
- 5) Continue research effort to develop alternatives to the PCB's and modify PCB's to make them biodegradable in conventional secondary waste treatment facilities.

Since that time, Monsanto reports that all sales of PCB's to applications where the disposal of the end product cannot be controlled have been discontinued, and that the complete range of fire-resistant hydraulic fluids has been reformulated to exclude PCB's. Furthermore, Monsanto, though it is continuing to sell PCB's for use in closed systems applications (e.g., transformers, capacitors, and heat transfer fluids), has agreed to cooperate with its customers in control of possible emissions from these applications. They are establishing a service to collect spent fluids for return to Monsanto to be regenerated or

destroyed in a specially designed, high-temperature incinerator. This service began operation July 1971.

Control Options

As sole U.S. supplier of PCB's Monsanto retains the option, at least at present, of controlling their distribution. It may continue to sell PCB for industrial uses which they say can be controlled, or they may voluntarily discontinue all sales of PCB's. Voluntary termination would probably occur if their concern with accidental contamination from remaining uses coincides with development of viable and marketable alternatives to PCB's. Involuntary termination of all sales could occur if EPA is given the authority to restrict the spread of toxic substances through pending legislation.

D. PCB's in Work Environments: Existing Controls

Occupational Safety and Health Administration (OSHA)--Department of Labor (DOL)

In compliance with their standard setting responsibility, OSHA published (May 29, 1971) a long list of recommended Threshold Limit Values (TLV's), including limits for PCB's as follows:

Chlorodiphenyl (42% Chlorine) - Skin 1 mg/M³*

Chlorodiphenyl (54% Chlorine) - Skin 0.5 mg/M³*

(*Approximate milligrams of particulate per cubic meter of air.)

These standards become effective on February 15, 1972, though the DOL can respond to complaints threatening "imminent danger" to health or safety prior to the effective date. Unless these TLV's are changed before the effective date, the DOL has authority to enforce them via inspection of employers' establishments and records, issuance of citations and imposition of penalties where applicable. According to Dr. Herbert Stokinger, chief of DHEW's Laboratory of Toxicology and Pathology for occupational health, there is no current concern with changing the toxicity standards for PCB's.

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Control Options

OSHA has the option to set additional standards for PCB's in work environments. The current level has been set to control the development of acne from skin exposure to PCB's. Additional research would be needed to substantiate standards for inhalation of PCB particles. Drinking of PCB's is not considered hazardous, and ingestion of PCB's in foods is already under USDA and FDA control.

E. PCB's in Air and Water: Control OptionsOffice of Air Programs (OAP) - Environmental Protection Agency

The Office of Air Programs is considering the inclusion of PCB's on a list of hazardous air pollutants, which they have authority to control according to the Clean Air Act Amendments of 1970 (42 U.S.C. 1857, Sec. 112). Asbestos, beryllium and mercury were placed on the list March 31, 1971, and other pollutants such as cadmium, nickel, and PCB's will probably be designated in mid-1972, or as soon as EPA assesses their health effects. If PCB's are designated in 1972, EPA must propose emission standards within six months after listing. Within another six months after proposing standards, EPA must promulgate final standards. These become effective upon promulgation for new sources and modifications of existing plants. Existing sources are not bound until 90 days after promulgation. Therefore, airborne emission standards for PCB's may be in effect by mid-1973, according to this maximum timetable.

Since PCB's are used as plasticizers, they may be released when certain plastics and other products are incinerated. Therefore, they will be controlled by EPA insofar as they are an emission from a stationary incinerator. On March 31, 1971, incinerators of more than 2,000 pounds per hour charging rate (municipal-type) were designated as a stationary source subject to standards of performance under Sec. 111 of the new Clean Air Act Amendments of 1970 (PL-604). Particulates and visible emissions will be the first incinerator pollutants to be regulated. PCB's apparently do not burn but are vaporized and collect on particulate matter, presumably in incinerator stacks. Therefore,

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they will probably be regulated by EPA by the end of this year if current research shows them to be a particulate emission. EPA was requested to propose the particulate standard of performance for incinerators by July 29, 1971, but the standard has not been set. By October 27, 1971, the standard must be promulgated. It will then become unlawful for any owner or operator of a new stationary pollutant source to operate in violation of the performance standard. Under the same Clean Air Amendments (Sec. 111(d)(1)) existing incinerators become liable to similar controls by states once the federal government establishes the new source performance standard.

By these avenues, any existing air emissions of PCB's will soon be regulated by the federal government, both as a hazardous pollutant and as an incinerator emission.

Office of Water Programs (OWP) - Environmental Protection Agency

The Oil and Hazardous Materials Division of the Office of Water Programs will probably designate PCB's as hazardous water pollutants before the end of 1971. This office has primary responsibility under Sec. 12 of the Water Pollution Control Act (33 U.S.C. 446 et seq.) for control of water-borne hazardous substances, and is charged with promulgating regulations dealing with the prevention, control and cleanup of hazardous substances discharged into navigable waterways and other waters. The hazardous substances list is long overdue but the final draft now under review establishes three categories of hazardous substances: inherently dangerous substances, such as heavy metals and Class A and B poisons; circumstantially hazardous substances, where the amount and circumstances of the discharge will be weighed, relative to danger; and any substance that violates water quality criteria. It is likely that PCB's will be designated as inherently dangerous substances, and any discharge of PCB's into waterways will be prohibited.

Once designated, the OWP has three legal options for control of the pollutants: (1) Applying emission regulations on hazardous substances to industries requesting discharge permits from the U.S. Army

Corps of Engineers, as required by the 1899 Refuse Act; (2) Using Sec. 10 of the Water Pollution Control Act, which calls for compliance with water quality standards and provides for the issuance of 180-day notices and (long) multi-sessioned conferences for abatement; and (3) Using Sec. 12 of the same Act, whereby regulations and contingency plans for the prevention and removal of discharges of hazardous materials would be developed by the OWP and the U.S. Coast Guard.

It is likely that EPA will exercise both options (1) and (3), since they require less time than option (2). Some form of effluent guideline or standard for PCB's will be established by EPA for use by the Corps of Engineers, and it is likely that no PCB effluents from any industry will be allowed when the discharge permit system goes into effective operation, i. e., by mid-1972.

A regulation and contingency plan for the prevention and removal of PCB's will be developed by the OWP and enforced by the Coast Guard. The Coast Guard has already submitted a report to Congress on the responsibility for the cost of removing such substances and on methods and measures for the prevention of such discharges. A National Contingency Plan for dealing with these discharges was originally promulgated by the Council on Environmental Quality in June, 1970. The Plan, now being revised by the CEQ, sought to establish and coordinate a national and regional network of contingency teams and plans to control and remove discharges of oil and hazardous substances. It included provisions for nuclear pollution and required articles to be prepared on "concentrations of potentially hazardous trace materials, including lead, chromium, zinc, arsenic, mercury, nickel, copper and chlorinated hydrocarbons," and a description of the analytical methods used to determine such concentrations.

II. Research Status

A. Food and Drug Administration

FDA research into PCB's is in a state of flux, perhaps due to the recent episode of food contamination. According to Dr. H. F. Kraybill, Assistant Director for Scientific Coordination, an interagency meeting will be held August 4 to evaluate the research priorities on PCB's. He has emphasized that not enough is known of existing levels of PCB food contamination and its presence in human and animal organs. Some work has been done by FDA on analytical methods to determine PCB content in various foods. However, according to J. William Cook, Director of the Division of Chemical Technology, they are admittedly not doing much toxicological work on PCB's, since Monsanto is rather heavily involved in this. Nevertheless, the following research programs are contemplated for fiscal year 1972:

- Polychlorinated Biphenyls and related compounds
- Teratogenic potentials in chick embryo, hamster, dog and swine
- Path exam. PCB terata
- Enzyme induction of Aroclor 1260 in dogs and mini-pigs
- Plant and animal metabolites of PCB and related compounds
- Enzyme induction of PCB in rats
- Path exam PCB: rats
- Measurement of residues of PCB and related compounds
- Chemical alteration products of PCB and related compounds

Apparently they are adopting a similar route with PCB's as they did with DDT, though they have smaller expectations for PCB contamination and effects than found with the pesticides. In answer to criticisms of FDA research activity in PCB, Dr. Kraybill would argue that they have limited resources, and that people have been screaming more loudly about mercury and heavy metals than about PCB's. FDA's sense of urgency in this regard may change after they evaluate what is known about PCB's this week.

B. Department of Agriculture

The Department of Agriculture has little involvement in research dealing with toxic contamination of foods. Most of this is performed by FDA and other research establishments. However, Dr. George Fries of the Dairy Cattle Branch, Animal Sciences Research Division, Agriculture Research Service, has been conducting a PCB feeding experiment with cows to detect PCB levels in milk. This will be completed in September, 1971. Of course the milk has been found to be contaminated, but if kept within the permissible level of 5 ppm in milk fat (which translates into .2 ppm in whole milk), Dr. Fries expects little, if any, effect on the cows. He notes that milk has been taken off the market in various places, often because the animal feed became contaminated with PCB's from the paint inside silos. This is apparently a common problem. He has published some of his findings, and has another publication pending.

C. Monsanto

Monsanto has been involved in a number of studies dealing with PCB's, most of which will be completed by the end of this summer. Two research efforts deal with the biodegradability of PCB's. One involves a Wales shake-flask study to determine which of the isomers in PCB's are persistent and which will break down. In their St. Louis laboratories they have been conducting semi-continuous activated sludge studies, adding nutrients to the compounds to determine the persistent and degradable isomers. According to William B. Papageorge, Manager of Environmental Control, Monsanto also has in progress a continuing program to improve analytical methodology in order to better deal with the wide variety of PCB's and their various properties. Monsanto is also experimenting with animals to gauge the toxicity of PCB's. A two-year chronic feeding experiment was initiated for Monsanto by the Industrial Bio-test laboratory in Chicago, whereby dogs, rats and chickens have been fed 1, 10 and 100 ppm (parts per million) of one of three types of Aroclors (PCB's), namely, 1242, 1254, and 1260. Monsanto is sharing the information gathered from this with government toxicologists. This two-year study will be

completed this year, and Dr. Papageorge has indicated that Monsanto is most willing to share all the information they have found. Some results were presented at a meeting of the Society of Toxicology (Medical College of Virginia, Richmond, Va. 23219), and more information on the results of their work will be coming out in a paper later this year.

D. Office of Pesticides--Environmental Protection Agency

At their Gulf Breeze Laboratory in Escambia Bay, Florida, EPA scientists have just completed nearly a year's work on Aroclor 1254, which was discharged into Escambia Bay via an accidental spill in 1968 from a Monsanto nylon plant. The PCB's, used as a heat exchange fluid in this instance, escaped from a cooling water ditch. Since then, the fluid used by the plant has been changed. According to Dr. Nelson Cooley of the lab, a wide variety of animals were tested for toxicity, including protozoa, shrimp, oysters and some fish. None of the levels of PCB's in these animals were found to be high enough to be noticeably toxic. Two articles have been published, reporting on these tests. One by Dr. Del Nimmo et al., "PCB's in Sediments," in a British journal, Nature; and a paper on "Aroclor 1254 in Water Sediments and Biota of Escambia Bay, Florida," by Messers Duke, Lowe and Wilson, in the Bulletin of Environmental Contamination and Toxicology, 1970.

E. Office of Air Programs--Environmental Protection Agency Health Effects

Under a \$19,078 contract to the Office of Air Programs, the South Carolina State Board of Health in Columbia, S. C. has undertaken an assay of human tissues for trace metals and PCB's. According to Dr. Douglas I. Hammer, Division of Effects Research, (EPA), and project manager for this contract, PCB's have been found to be a mirror image of DDT. That is, where DDT is highest in concentration in rural blacks, PCB's are highest in concentration in urban whites, reflecting the fact that they are an industrial (urban) rather than agricultural (rural) contaminant. A new contract was granted to the South Carolina State Board for more extensive continuation of this work. Information on the new contract is available from Dr. Priester, 803-758-5420.

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Source Control

The Division of Applied Technology, in cooperation with other OAU offices and research services, has been sampling and testing emissions from six incinerators to compile emission data in order to set new source emission standards on particulates and visible emissions from incinerators. The six incinerators sampled were incinerators in Dade County, Fla., Braintree, Mass., Paris, Dusseldorf and two in New York City. (The tests cost roughly \$15,000 per incinerator.) All testing and sampling should have been completed before the end of July, 1971, when EPA was required to propose emission standards. Air pollution staff have been mostly concerned with gathering data on the PCB content of incinerator effluent. Information on the toxicity of these compounds has been insufficient to justify setting permissible levels of emission. It is suspected that PCB's from incinerators enter the atmosphere as an aerosol, that is, begin as a vapor but end as a solid.

F. Bureau of Wildlife and Sports Fisheries--Department of Interior

At the Bureau's Patuxent Wildlife Research Center in Laurel, Maryland, PCB's in birds have been analyzed routinely for several years. Two publications are available on their research, one of which deals with the identification of structural formulas for 18 PCB's found in eagle tissues. They have also been conducting several two-year studies on the effects of PCB's on reproduction of game birds. They have tested for all combinations of PCB's and have attempted to measure the toxicity of PCB on four species of game birds.

According to Dr. Lucille Stickel, Pesticide Research Coordinator at the Center, PCB's were identified in 1966 and they have been aware of them for several years. Several papers have been published on their research activities, but she emphasizes that their evaluation is not yet complete. So far, however, they have discovered no reproductive effects of PCB's, though some evidence of this has been found in chickens.

The Bureau's Pesticide Research Laboratory in Columbia, Mo., has investigated acute toxicities of PCB's on trout and bluegills, where

Dr. Richard Schoettger has reported that PCB's have a relatively low acute toxicity. Dr. David Stallings of the same lab has been working on analytical procedures for PCB's and will do more work on game fish in this area.

G. Office of Science and Technology--Executive Office of the President

The Office of Science and Technology is actively engaged in a number of case studies concerning a variety of toxic organic and inorganic substances, including PCB's. Their general purpose is to evaluate the information available on PCB's in order to give advice and assistance to the President with respect to developing policies and programs dealing with these substances. Dr. Edward Burger is especially concerned with PCB's and related substances, but has stressed that at this time they are grappling with an information problem; that is, with the problem of not knowing where PCB's are found, and what their effect is. It is not likely that their work in this area will become available to the public.

H. Other

In addition to the above, significant research has been previously performed on PCB's by the Kettering Laboratory at the University of Cincinnati (Dr. J. F. Treon), and by Professor E. L. McCune and his co-workers at the University of Missouri. Dr. Treon's group investigated acute toxicities of PCB's on animals, and Prof. McCune discovered the toxic effect of PCB's on chickens. According to Monsanto, between 100 and 150 laboratories have requested material from them on PCB's. A great deal of existing research activities are still focusing on analytical methods for determination and identification of PCB's in the biosphere.

IV. SUMMARY OF SENATE COMMERCE COMMITTEE HEARINGS

I. Hearings

On August 3, 4 and 5th the Senate Commerce Subcommittee on Environment held hearings on S 1478, the Administration's Toxic Substances Control Act of 1971. Senator Spong (D-Va.) introduced an amendment to the bill which was also considered at the hearings. Although the Subcommittee is chaired by Sen. Hart (D-Mich.), Sen. Spong presided over the hearings. The only other Senator at the hearings was Sen. Hatfield (R-Ore.).

Generally, the hearings were low key as environmentalists, administration spokesmen, and scientists presented less than dramatic testimony. Industry did not testify at these sessions of the hearings, preferring to wait until October testimony. Sen. Spong did not run the hearings in an adversary manner and did not press witnesses on the weak points in their testimony. Sen. Hatfield was largely out of the questioning and preferred to ask broad policy and general environmental questions. The committee staff, who had written the Spong amendments, did not participate in the questioning although they were present at the hearings.

II. Tuesday, August 3

The first day of hearings had only two witnesses: Russel Train, the Chairman of the President's Council on Environmental Quality and Dr. David H. Klein, of Hope College in Michigan.

Train discussed the need for the administration bill and cited examples of pollution that could only be effectively controlled through the new authority of the bill. Train cited PCB and cadmium hazards as examples for the need to control the use and distribution of substances rather than control their effects after they enter the environment. Commenting briefly on the Spong amendment, Train said CEQ did not favor the added authority of pre-market clearance, mandatory reporting of tests, etc. as it would make administrative procedures cumbersome. This would

lessen the effectiveness of the enforcement of the most significant hazardous substances. However, Train did say that CEQ welcomed the addition of Spong's citizen suit clause.

Spong questioned Train on how the act would apply to consumer products. Train noted that the bill was not intended to supplant existing consumer protection authority and would apply to industrial chemical substances generally. Spong revolved the questioning around the differences between the administration bill and his amendments.

Dr. Klein, a professor of chemistry and noted expert on mercury pollution, testified that municipal sewerage systems are faced with large amounts of mercury from normal sewerage that they cannot treat effectively. While EPA and state governments have dramatically cut the industrial discharge of mercury, nothing has been done for other, overlooked sources. Since this source of mercury comes from batteries, hospital and college labs, pharmaceuticals, disinfectants and various household uses, the proposed bills could provide the authority to control such pollution.

III. Wednesday, August 4

Robert Fri, Deputy Administrator of EPA, presented testimony in support of the administration bill. Spong asked him about his amendment provision for citizen suits and Fri said that EPA would accept such an amendment.

Robert Risebrough, a Research Ecologist at the Bodega Marine Laboratory of the University of California, presented a detailed scientific paper on PCB. His testimony, for the most part, was objective and fair and did not contain alarmist warnings. The gist of the testimony was that more research is needed to determine why PCB is connected with certain health effects, and one way to do this would be through the testing procedures of the proposed bills. While he gave examples of the harmful effects of PCB contaminated rice oil in Japan, he noted that

it was not clear whether the effects were produced by the PCB or by very small amounts of other contaminants (benzofurans, dibenzofurans, dibenzodioxins). For the most part, Risebrough's testimony was not the type that manufacturers have come to expect from pro-control witnesses, and representatives of Monsanto (the sole manufacturer of PCB in the U.S.) and the Manufacturing Chemists Association liked the low key tone of the testimony and hearings in general.

The most dramatic moment of the hearings came during Risebrough's testimony. Sen. Spong released correspondence from the Alabama Game and Fish Division which detailed FDA test results showing PCB contaminated fish 72 times the tolerance set by FDA. The FDA did not release the statistics although the tests were made in 1970. It is presumed that the fish were contaminated by the sewerage discharge of a nearby Monsanto plant.

Again the PCB example fitted into the testimony because its contamination results from situations where existing legislation is largely ineffective. Risebrough emphasized the need for the proposed amendment to control the use and distribution of chemicals like PCB.

An environmental group panel consisting of Harrison Wellford, a Nader associate; Linda Billings, Sierra Club; Samuel Love, Environmental Action, Louise Dunlop, Friends of the Earth, and Joel Pickelner, National Wildlife Federation, also was heard. While presenting separate testimony, all strongly preferred the Spong amendment. Suggestions to strengthen it were offered. Among them were the inclusion of pesticides, extending the authority to exports (both bills exempt exports) and spelling out when the administrator of EPA is required to act (rather than leaving it to his discretion).

IV. Thursday, August 5

Dr. William Nicholson from Mt. Sinai Hospital, New York testified on the health hazards of asbestos. While noting that only certain uses of

asbestos present a hazard, the proposed legislation could be helpful in regulating those instances. Nicholson also said that gaps in knowledge about asbestos tolerance levels and related information could be overcome by systematic testing protocols and procedures, which the bills provide.

A public interest law panel, consisting of Robert Hallman, Center for Law and Social Policy; Karin Sheldon, Public Interest Research Group; William Rogers, Univ. of Washington, Law School; Edward Strobehn, Natural Resources Defense Council; and John Dinealt, Environmental Defense Fund, also discussed the proposed legislation. Generally they supported the Spong amendment and felt that pesticides and exports should not be excluded from the authority of the bill. A better system to insure objective testing was also suggested.

V. SUMMARY OF HOUSE PUBLIC HEALTH AND ENVIRONMENT COMMITTEE HEARINGS

I. House Oversight Hearings

Rep. Paul G. Rogers' (D-Fla.) subcommittee on Public Health and the Environment, of the House Interstate and Foreign Commerce Committee, held two days of oversight hearings August 3 and 4 on federal food inspection and testing activities. Rogers' primary interest during the two day session was with procedural and administrative questions surrounding current government inspection practices. He and the rest of the subcommittee exhibited little interest in specific problem areas of food quality, concentrating instead on the development of alternative systems of inspection and testing to increase general levels of food safety.

II. August 3

The first day of hearings was devoted to testimony by Dr. Charles Edwards, Commissioner of the Food and Drug Administration. Edwards' testimony concentrated on the severe shortage of inspectors and money which FDA faces, and indicated that crisis situations, such as the Bon Vivant recall campaign, force cancellation of a large number of already infrequent regular inspections. No mention was made of the PCB problem, either by FDA representatives or by the subcommittee.

III. August 4

The second and final day of hearings considered testimony by Peter Shuck of the Center for the Study of Responsive Law and Robert Vaughn of the Public Interest Research Group. Shuck and Vaughn delivered strong attacks against the current inspection and testing practices carried out by FDA and the Department of Agriculture, citing a variety of occurrences of chemical or microbiological contamination to illustrate their charges. Shuck, who handled the chemical contaminant portion of the presentation, devoted approximately 20 per cent of his testimony to PCB's, utilizing horrifying but largely unsupported examples of the consequences of PCB ingestion.

Shuck strongly criticized the use of PCB's under any circumstances. He said that despite assurances from Monsanto that PCB's are not sold for use as pesticides, and that industrial use of the chemicals occurs largely in "closed systems," contamination is a real and continuing possibility. He cited the Eastern Terminal situation, in which PCB's allegedly were introduced into chicken feed from a faulty "closed system" as evidence that current controls over the chemicals are inadequate.

The subcommittee expressed only slight interest in the PCB situation, except as it demonstrated a need for reform of current inspection and testing practices. Rep. Rogers indicated that he would write a letter to the Department of Agriculture and attempt to ascertain why current procedures were inadequate for the problem presented by PCB contamination.

VI. LEGISLATIVE OUTLOOK

I. Outlook

The Administration has introduced the Toxic Substances Control Act of 1971 (HR 5930, S 1478), a bill to control the use and distribution of toxic substances from manufacture through distribution. Senator Spong (D-Va.) has introduced a major amendment (No. 338) to the bill which would strengthen the control authority by requiring pre-market clearance and a method for systematic testing of existing substances. Sen. Muskie has introduced a similar bill (S 573) as has Rep. Vanik (D-Ohio) (HR 7445). Bills to ban PCB entirely have been introduced by Rep. Ryan (D-N.Y.).

Interest has centered around the Administration bill and the Spong amendment. Hearings have been held on these bills before the Senate Commerce Subcommittee on Environment, with Sen. Spong presiding. Muskie has agreed to delay hearings on his bill until the Commerce committee hearings are completed.

There is little likelihood that either the Senate or House will pass a toxic control substances bill this session. The Senate will resume hearings in October and there is little chance that a clean bill will be reported out in enough time for a Senate vote this session. The House has not assigned any of the toxic substances control bills to a subcommittee so there is even less likelihood of hearings, much less passage in the House. It is anticipated that Muskie will not hold hearings on his bill even after the Commerce committee finishes, so only S 1478 and the Spong amendment will be considered by the Senate. The Ryan bills to ban PCB production are not expected to attract widespread support.

II. Administration Proposal (HR 5030, S 1478)

Bills have been introduced which approach the hazardous substances issue from several angles. The most comprehensive approach is the Administration's Toxic Substances Control Act of 1971 (HR 5030, S 1478). The bill is based on a comprehensive review of the subject by the Council on Environmental Quality. The premise of the Act is new. It shifts the hazardous substances issue from media (air, water, food, products, etc.) to the pollutant itself and proposes to empower EPA to control the substance from its initial production, through distribution and disposal.

The bill amends the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.), a labelling law with limited removal and restrictive powers. The bill would authorize the Administrator of EPA to:

- 1) restrict or prohibit the use or distribution of a chemical substance produced in commercial quantities in order to protect the health or environment;
- 2) to request a court injunction in the event of an imminent hazard (loosely defined as a threat requiring immediate abatement) caused by the substance;
- 3) to issue standards and tests that new substances would have to meet before being marketed;
- 4) to require from manufacturers, reports on the names, chemical composition, production level, uses and results of tests on the health and environmental effects of the substance;
- 5) to conduct research, to develop an information system, and to predict and assess capability; and
- 6) to enter and inspect facilities connected with the production or storage of hazardous substances.

A Toxic Substances Board would be established in EPA to advise the Administrator on action taken under the Act. Civil and criminal penalties up to \$25,000 and one year imprisonment could be assessed for violations. The bill exempts substances solely intended for export, economic poisons under the Federal Insecticide, Fungicide, Rodenticide Act (7 U.S.C. 135a et seq.), substances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Comprehensive Drug Abuse Prevention and Control Act of 1970 and materials under the Atomic Energy Act of 1954. The Act would not apply to the Department of Transportation's power to establish rules and regulations for the transportation of hazardous materials, nor to the regulatory authority of the Occupational Health and Safety Act of 1970 regarding hazards to employees. The Act would also not apply to the regulation of the household use of marketed products which might contain the substance. In cases outside of the Act's authority where evidence of potential hazard is found, EPA is to notify the appropriate federal agency. The Administrator of EPA is also charged to use the Water Pollution Control Act and Clean Air Act in enforcing the proposed Act.

Spong Amendment to the Toxic Substances Control Act of 1971 (S 1478)

The amendment keeps the basic authority of the Administration bill to control substances through testing standards and usage restrictions. However it tightens definitions, adds a pre-market clearance requirement, makes it easier to apply the testing requirements to existing substances, includes provisions for citizen suits and enables EPA to take legal action without going through the Department of Justice.

Certification (Pre-market clearance): Manufacturers of new chemical substances must obtain a certification from EPA that the substance has met the test standards. EPA may require the results of the tests and any

other information to arrive at certification. The Administration bill has no certification procedure or other check to insure that the required tests have been completed or adequately conducted.

Existing Substances: The Administration bill does not require that existing substances be tested and meet the promulgated standards. It also does not provide a method for starting the testing apparatus. The Spong amendment includes authority for the Administrator of EPA to promulgate test standards for existing substances when he has "reason to believe" that such substances may "pose an unreasonable threat to man or the environment." Both bills authorize restrictions on the use or distribution of all chemical substances (new and existing) to protect health and the environment, including prohibiting sale and use.

Other Changes: The recall of products containing the substance in violation of any standards is added in the Spong amendment, and seizure powers are provided in cases deemed imminent hazards. The EPA Administrator is given authority to issue Administrative orders against the threat imposed by imminent hazards, instead of going through the courts. Citizen suits are authorized if EPA fails to act upon a mandatory duty. EPA could initiate legal actions without the Department of Justice. The amendment explicitly gives EPA authority to regulate consumer products containing regulated substances (this was unclear in the Administration bill).

III. Maskie Bill (S. 573)

The Maskie bill amends the Clean Air Act and Water Pollution Control Act to control the use of hazardous substances in manufactured products and to require pre-market testing of new substances. The bill is similar to the Administration proposal and includes test standards and reporting and record-keeping requirements. Condemnation and seizure is authorized for violations of standards. Like the Administration bill the Administrator of EPA can make inspections and enter premises to obtain samples.

The bill was cast in terms of air and water pollution control to enable Muskie to preside over its hearing before his Public Works Subcommittee on Air and Water Pollution. The bill is still in executive session and hearings have not been scheduled. The fact that the Administration bill is being considered by the Senate Commerce Subcommittee on the Environment increases the likelihood that the Muskie bill will not see action this session. In fact, Muskie has agreed to withhold hearings until the Commerce Committee is finished with its hearings, which is not expected to be until sometime in late September or early October.

IV. Other Proposals

Vanik Bill (HR 7445): Rep. Charles A. Vanik (D-Ohio) introduced the Polluting Substances Control Act of 1971. The bill is similar to the above bills but gives authority to the Secretary of HEW to regulate and require pre-testing of new substances. The bill has not been scheduled for hearings by the House Committee on Interstate and Foreign Commerce.

Ryan Bills (HR 8576, HR 10085): Rep. William Ryan (D-N.Y.) has been the most outspoken critic of PCB contamination on the Hill. On May 19, 1971 he introduced a bill to prohibit the introduction of PCB into commerce except in carefully controlled operations. Both the manufacturer (Monsanto) and receiver would be required to keep records on the quality of PCB used. The Secretary of HEW would administer the Act. This bill legislated what Monsanto (the sole U. S. manufacturer) has already done voluntarily: restrict the sale and usage of PCB's to closed systems and other environmentally safe uses.

Ryan later introduced a bill (HR 10085) to prohibit the manufacturer of all PCB. This was done after the chicken feed situation convinced Ryan that no certain way to control PCB existed at this time. Both bills

have been assigned to the Commerce Committee, but there is little likelihood that hearings will be held on these specific bills. A member of Ryan's staff said that he had little hope that the bill would pass. Rather the expectation is that it will spur administrative action to control PCB and thus make legislative action unnecessary. A lesser hope is that the control provisions would be incorporated into a larger, general toxic substances control bill.

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